NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| ENDO PHARMACEUTICALS, INC., | **Hon. Dennis M. Cavanaugh** |
| Plaintiff, | **OPINION** |
| v. | Civil Action No. 12-cv-7591 (DMC) (MF) |
| ACTAVIS, INC., et al., | |
| Defendant. | |

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon Defendant Actavis, Inc. and Actavis South Altantic LLC (collectively "Actavis")'s Motion to Dismiss Plaintiff Endo Pharmaceuticals, Inc. ("Endo")'s Complaint (Jan. 22, 2013, ECF No. 6). Pursuant to FED. R. CIV. P 78, no oral argument was heard. Based on the following and for the reasons expressed herein, Defendant's Motion is **granted without prejudice.**

## I. BACKGROUND[1]

Endo's Opana ER® was approved by the Food and Drug Administration ("the FDA") in 2006 as a prescription extended release opioid pain reliever. Actavis is a generic pharmaceutical company that manufactures, markets, and sells Oxymorphone Hydrochloride Extended-Release Tablets CII. Actavis's generic is a non-crush resistant extended release oxymorphone painkiller developed as a generic version of the original Opana® ER formulation which the FDA gave an AB rating to Opana® ER's original formulation. In May 2012, Endo developed a re-formulated

[1] This section comes from the Complaint and the parties pleadings.

version of Opana® ER that is designed to be crush-resistant ("CRF version of Opana® ER").

According to the Complaint, an "AB Rating" signifies that the FDA has approved a generic drug as being bioequivalent to, and as safe and effective as, the specified brand-name drug. Endo alleges in the Complaint that Actavis's generic tables "are not and have never been AB rated to the only Opana® ER tablets sold by Endo since May 2012, i.e., the crush resistant tablets, and those Generic Oxymorphone ER tablets are not designed to be crush-resistant like Opana® ER." (Compl. ¶ 7). Endo further alleges that Actavis's false statements have caused and are continuing to cause harm to both Endo and the public, by causing Actavis's generic oxymorphone ER tables to be substituted for Endo's CRF version. (Id. ¶ 8).

Endo alleges that despite the fact that its Generic Oxymorphone ER Tablets are not crush resistant, and were not approved based on the current Opana® ER New Drug Application ("NDA"), Actavis is falsely marketing its generic product as "AB Rated to Opana® ER."

Endo filed the instant Complaint against Actavis on December 11, 2012 (ECF No. 1). Actavis filed this Motion on January 22, 2012 (Actavis Br., ECF No. 8). Endo filed a Brief in Opposition and a Cross Motion for Partial Summary Judgment on February 5, 2013 (Endo's Opp'n, ECF No. 15). Actavis filed a Reply Brief on February 13, 2012 (Actavis Reply 18). 11, 2013 (Actavis Reply, ECF No. 26) On March 4, 2013, Actavis filed a separate brief in Opposition to Endo's Cross Motion for Summary Judgment (ECF No. 21).

Thereafter Endo filed a brief in Reply in Support of Endo's Cross Motion for Summary Judgment. (Mar. 11, 2013, ECF No. 26). Actavis then moved to strike the declarations in Endo's Reply. (Mar. 19, 2013, ECF No. 28). L. Civ. R. 7.1(d)(3) provides that no reply papers shall be filed, unless permitted by the Court, for a cross motion under L.Civ.R. 7.1(h). Consequently the Court will not consider Endo's Reply Brief to its Cross Motion as this Court did not grant

permission for such filing and the Motion to Strike is thus moot (Mar. 19, 2013, ECF No. 28).

## II. STANDARD OF REVIEW

In deciding a motion under FED. R. CIV. P. 12(b)(6), the District Court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." Phillips v. Cnty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). However, the plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions and a formulaic recitation of the elements of a cause of action will not do." Id. On a motion to dismiss, courts are "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986). Plaintiff's complaint is subject to the heightened pleading standard set forth in Ashcroft v. Iqbal:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . Determining whether a complaint states a plausible claim for relief will. . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not "show[n]" - "that the pleader is entitled to relief."

Ashcroft v. Iqbal, 556 U.S. 662, 678-679 (2009) (quoting Twombly, 550 U.S. at 557, 750).

## III. DISCUSSION

Actavis argues that Endo's claim about AB-ratings cannot be adjudicated in a Lanham Act case between private parties because it is bound-up with determinations that can only be made by FDA under the Food, Drug & Cosmetic Act, which does not authorize a private right of action. Actavis argues:

> Because attempts to adjudicate these issues in suits between competitors would (i) undermine FDA's ability to act as regulator by substituting the judgments of judges and juries for expert determination by the agency's professional staff, and (ii) defeat the purpose of constituting FDA as the sole entity with authority to make these determinations (hence no private right of action under the FD&C Act), private parties cannot seek what are effectively FDA-like determinations in the guise of Lanham Act challenges to their competitors' characterization of FDA-approved drugs.

(Actavis Br. 6). Endo argues that it is not asking the Court to make any scientific determination or otherwise decide any issue that would interfere with the FDA's authority, but instead "will only require the Court to determine an existing fact – i.e., whether Actavis's Tablets are listed by FDA in the Orange Book as being AB rated to Opana® ER." (Endo Opp'n Br. 12).

The doctrine of primary jurisdiction is applicable when an action that is otherwise within the court's jurisdiction raises some issue of fact that falls within the expertise and experience of an administrative agency. Reiter v. Cooper, 507 U.S. 258, 268 (1993). Actavis relies primarily upon Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222 (3d Cir.1990) in arguing that the doctrine of primary jurisdiction applies here. In that case, the Third Circuit was called upon to determine whether the defendant's listing of the demulcents in the cough syrup it manufactured as "inactive" on the product's label was false. Id. at 230. However, the FDA had not yet addressed whether demulcents must be labeled as "active" or "inactive" ingredients within the meaning of its regulations. Id. In the absence of such guidance from the FDA, the court found that plaintiff's position "would require [it] to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations." Id. at 231.

The Court agrees with Actavis and declines to make a determination whether Actavis's generic is still AB equivalent to Opana® ER or whether the new CRF formulation changes this designation. Notably, Endo agrees that FDA approved Actavis's generic with an AB therapeutic equivalency rating to Opana® ER. (Endo Opp'n Br. 4, 9). Endo does not contend that FDA

revoked the AB rating. This Court defers to the FDA to determine whether the new formulation of Opana® ER is no longer AB equivalent to the generic Actavis product. The Court also notes that an application has been made to the FDA on this issue, and it would be improper for the Court to make a determination on this matter before the FDA has had an opportunity to do so. Thus Actavis's Motion to Dismiss is granted without prejudice.

## IV. CONCLUSION

For the reasons stated above, Actavis's Motion to Dismiss is granted without prejudice. An appropriate Order accompanies this Opinion.

Dennis M. Cavanaugh, U.S.D.J.

Date: ~~August~~ Sept 3, 2013
Original: Clerk's Office
cc: Hon. Mark Falk, U.S.M.J.
All Counsel of Record
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